

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

|                             |   |                             |
|-----------------------------|---|-----------------------------|
| HARBOUR ANTIBODIES BV,      | ) |                             |
| HARBOUR ANTIBODIES HCAb BV, | ) |                             |
| ERASMUS UNIVERSITY MEDICAL  | ) |                             |
| CENTER ROTTERDAM, DR. ROGER | ) | Civil Action No. 21-1807-MN |
| KINGDON CRAIG,              | ) |                             |
|                             | ) |                             |
| Plaintiffs,                 | ) |                             |
|                             | ) |                             |
| v.                          | ) |                             |
|                             | ) |                             |
| TENEOBIO, INC.,             | ) |                             |
|                             | ) |                             |
| Defendant.                  | ) |                             |

**MEMORANDUM ORDER<sup>1</sup>**

At Wilmington this **28th** day of **January, 2025**, the court having considered the motion for leave to amend the complaint (D.I. 200), the associated filings (D.I. 188; D.I. 190), the prior rulings issued in this case (D.I. 70; D.I. 161), and the parties' arguments presented during the hearing on January 27, 2025, the motion for leave to amend the complaint is GRANTED for the following reasons:

**1. Background.** Plaintiffs Harbour Antibodies BV ("HBV"), Harbour Antibodies HCAb BV ("HBAB;" together with HBV, "Harbour"), Erasmus University Medical Center Rotterdam ("Erasmus"), and Dr. Roger Kingdon Craig ("Craig;" collectively, "Plaintiffs") filed this patent infringement action against defendant Teneobio, Inc. ("Teneobio") on December 23, 2021, alleging that Teneobio's UniRat® platform infringes four patents covering Harbour

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<sup>1</sup> "Motions for leave to amend pleadings are typically treated as 'non-dispositive' applications within the pretrial powers of a magistrate judge on referral," unless the motion for leave to amend is denied. *Smith v. State of Del.*, C.A. No. 07-600-JJF-LPS, 2009 WL 2175635, at \*1 n.2 (D. Del. July 21, 2009).

Mice®, a platform technology that utilizes transgenic rodents to generate functional heavy-chain only antibodies (“HCAbs”) for therapeutic or research purposes. (D.I. 1 at ¶¶ 1, 3; D.I. 161 at 3)

2. On August 6, 2021, several months before this lawsuit was filed, DLA Piper (US) was asked to represent Plaintiffs in a potential action against Teneobio. (D.I. 161 at 3) Amgen, Inc. then acquired Teneobio on October 19, 2021, about two months before the instant case was filed. (D.I. 1 at ¶ 4 & n.2) After the case was filed, the parties engaged in alternative dispute resolution efforts in May of 2022, during which in-house counsel for Amgen became aware of a potential conflict and informed counsel from DLA Piper. (D.I. 161 at 4)

3. On June 7, 2022, Amgen’s General Counsel informed DLA Piper’s counsel that DLA Piper’s representation of Harbour gave rise to a conflict and requested that Harbour give an enforceable commitment to Amgen that it would not seek any injunctive relief or damages against Amgen in the action against Teneobio. (*Id.*) Harbour declined to make the requested commitment. (*Id.*)

4. On July 18, 2022, Teneobio moved to disqualify DLA Piper as Harbour’s counsel based on the firm’s longstanding and current representation of Amgen, Teneobio’s parent company. (D.I. 40) In response, Harbour maintained that their prayer for relief was against Teneobio, and any effect on Amgen would be derivative. (D.I. 50) Teneobio then sent a letter to Harbour in August of 2022 requesting a binding and enforceable commitment that Harbour would seek remedies and enforcement only against Teneobio, and not against any other Amgen entity. (D.I. 188, Ex. 5) Harbour rejected Teneobio’s proposal, maintaining that any effect of the litigation on Amgen would be derivative. (*Id.*, Ex. 3) Harbour reserved the right to pursue claims and remedies against third parties, including Amgen. (*Id.*)

5. A Report and Recommendation was issued on October 3, 2022 recommending that the motion to disqualify should be denied. (D.I. 70) On February 16, 2023, the case was stayed pending the resolution of foreign proceedings. (D.I. 121)

6. The stay was lifted on October 3, 2024. (D.I. 159) On October 16, 2024, the parties filed a stipulation disclosing that Plaintiffs were in the process of changing counsel. (D.I. 160 at 1; D.I. 161 at 1 n.1) On October 23, 2024, the court issued a Memorandum Opinion and Order adopting the conclusion of the Report and Recommendation and denying the motion to disqualify. (D.I. 159; D.I. 161; D.I. 162)

7. DLA Piper formally withdrew from its representation of Plaintiffs in November of 2024 and new counsel for Plaintiffs entered their appearances. (D.I. 163; D.I. 164; D.I. 165; D.I. 166; D.I. 172; D.I. 173) On December 9, 2024, the court entered an amended scheduling order setting a deadline of December 13, 2024 for amended pleadings. (D.I. 176)

8. It is undisputed that Plaintiffs sought leave to amend the complaint on December 12, 2024, before the deadline set forth in the scheduling order, but Teneobio opposed the request. (D.I. 190 at 3; D.I. 176) Consequently, Plaintiffs filed the instant motion for leave to amend the complaint to update the ownership of the asserted patents, provide technical clarifications, and allege that Amgen, as Teneobio's parent company, also willfully infringed the asserted patents. (D.I. 188 at 1; Ex. 1) The parties' dispute focuses on the proposed amendment of the complaint adding Amgen as a party accused of infringement.

9. **Legal standard.** Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that the court should freely give leave to amend the pleadings when justice so requires. Fed. R. Civ. P. 15(a)(2). The decision to grant or deny leave to amend lies within the discretion of the court. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Secs. Litig.*, 114

F.3d 1410, 1434 (3d Cir. 1997). In the absence of undue delay, bad faith, or dilatory motives on the part of the moving party, the amendment should be freely granted, unless it is futile or unfairly prejudicial to the non-moving party. *See Foman*, 371 U.S. at 182; *In re Burlington*, 114 F.3d at 1434. Futility is measured under the same standard applicable to a Rule 12(b)(6) motion to dismiss: “If the complaint, as amended, would not survive a motion to dismiss, leave to amend may be denied as futile.” *VLSI Tech. LLC v. Intel Corp.*, C.A. No. 18-966-CFC, 2020 WL 3488584, at \*2 (D. Del. June 26, 2020) (quoting *Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A. No. 13-2108-RGA *et al.*, 2016 WL 720977, at \*7 (D. Del. Feb. 23, 2016)).

**10. Analysis.** Teneobio opposes Plaintiffs’ motion for leave to amend for three reasons. Teneobio contends that the motion should be denied for Plaintiffs’ undue delay in seeking leave to amend, resulting in prejudice to Teneobio. (D.I. 190 at 2-3) Teneobio also alleges that Plaintiffs are judicially estopped from adding Amgen as a party to the case following the representations they made to the court during litigation on the motion to disqualify. (*Id.* at 1-2) Moreover, Teneobio argues that the proposed amendment would be futile because: (1) Amgen had a valid license to the asserted patents; and (2) Plaintiffs have not plausibly pled a cause of action for direct infringement by Amgen. (*Id.* at 2) For the following reasons, Plaintiffs’ motion for leave to amend is GRANTED.

**11. Undue delay and prejudice.** Plaintiffs argue their motion is timely because they sought leave to amend the complaint on December 12, 2024, one day before the deadline for amended pleadings set forth in the operative scheduling order. (D.I. 188 at 2; D.I. 176 at ¶ 2) Teneobio concedes that “Plaintiffs moved to amend before the deadline[.]” (D.I. 190 at 3) Nonetheless, Teneobio contends that Plaintiffs unduly delayed in bringing their motion to amend because they have known about Amgen’s acquisition of Teneobio since before this lawsuit was

filed, yet they waited until the day before the deadline for amended pleadings to seek leave to add Amgen as a defendant. (*Id.*) According to Teneobio, granting leave to amend at this stage of the proceedings would require renegotiation of the case schedule to obtain additional discovery and would result in significant delays to the resolution of the case. (*Id.*)

**12.** Although the parties agree that the good cause standard of Rule 16(b) does not apply because the request to amend was made within the time set forth in the scheduling order, Rule 15(a)(2) also requires an assessment of undue delay or dilatory motives on the part of the moving party. “[T]he question of undue delay requires [that the court] focus on the movant’s reasons for not amending sooner.” *Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A. No. 13-2108-RGA *et al.*, 2016 WL 720977, at \*7 (D. Del. Feb. 23, 2016) (quoting *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001)). Plaintiffs cite the appearances of their current counsel less than a month before they sought leave to amend as a reason for not amending sooner. (D.I. 188 at 2) The change in counsel is a valid reason for not amending sooner and distinguishes the facts of this case from the case authority cited by Teneobio.<sup>2</sup>

**13.** During the hearing on January 27, counsel for Teneobio represented that Plaintiffs had the necessary information for their proposed amendments in July of 2022, when they reviewed a declaration by Amgen’s in-house counsel (the “Diamond Declaration”) which was filed by Teneobio in support of its motion for disqualification. (1/27/2025 Tr.; D.I. 42 at ¶ 1)

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<sup>2</sup> At the hearing, both sides indicated that they found no analogous authority involving the appearance of new or substitute counsel shortly before the filing of a motion for leave to amend. (1/27/2025 Tr.) Counsel for Teneobio acknowledged that the cases it cited did not involve the appearance of new or substitute counsel shortly before the filing of the motion for leave to amend. See, e.g., *StrikeForce Techs., Inc. v. PhoneFactor, Inc.*, C.A. No. 13-490-RGA-MPT, 2015 WL 3793726 (D. Del. May 26, 2015); *Cureton v. Nat'l Colleg. Athl. Ass'n*, 252 F.3d 267, 273-74 (3d Cir. 2001); *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267 (3d Cir. 2004); *Jang v. Boston Sci. Scimed, Inc.*, 729 F.3d 357 (3d Cir. 2013).

The court is not persuaded by this argument. Plaintiffs did not engage in undue delay by waiting for full briefing, oral argument, the Special Master's Report and Recommendation, and the resolution of objections to the Report and Recommendation on the motion to disqualify before they moved to amend the complaint.

**14.** Neither Teneobio nor Amgen will be unfairly prejudiced by the amended pleading because this case is in its early stages and there is sufficient time in the scheduling order to accommodate additional discovery. *See Harbour Antibodies BV v. Teneobio, Inc.*, C.A. No. 21-1807-MN, 2024 WL 4554855, at \*8 (D. Del. Oct. 23, 2024). Teneobio suggests that “[t]he schedule would need to be completely re-negotiated to allow time for: Amgen to respond to the Amended Complaint and the Court to resolve any [Rule 12 motions]; the parties to seek additional discovery; and addressing any impact of the amendment on the parties’ claim construction positions.” (D.I. 190 at 3) But the current scheduling order provides that the joint claim construction chart is not due until May of 2025, and the *Markman* hearing is six months away. (D.I. 176 at ¶¶ 11, 13) There are three months left in the fact discovery period, case dispositive motions are not due until December of 2025, and trial is scheduled for June of 2026. (D.I. 176 at ¶¶ 8(a), 15(a), 20) During the hearing on January 27, the parties conceded that they have not yet conferred on how the proposed amendment will impact the case schedule. (1/27/2025 Tr.) Teneobio speculates that the additional discovery will be extensive, but the court finds there is sufficient time in the schedule to accommodate additional discovery.<sup>3</sup>

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<sup>3</sup> As for Rule 12 motions, it is well-established that the futility standard applied to a motion to amend the complaint is the same as the Rule 12(b)(6) standard governing a motion to dismiss for failure to state a claim. *See VLSI Tech. LLC v. Intel Corp.*, C.A. No. 18-966-CFC, 2020 WL 3488584, at \*2 (D. Del. June 26, 2020). Teneobio has challenged the proposed amendment on futility grounds, and the court has determined that amendment would not be futile for the reasons set forth below. Further accommodations to the case schedule can be made without disrupting the trial date to the extent that Amgen seeks further relief under Rule 12.

**15.** Moreover, Teneobio’s own filings demonstrate that Amgen is well-acquainted with the legal theories and evidence at issue in the case. In 2022, Teneobio submitted declarations confirming that Amgen “makes strategic decisions for Teneobio, including what outside counsel Teneobio will retain (including for this case)” and “makes all other decisions for this case (in collaboration with outside counsel hired by Amgen)[,]” and Amgen’s in-house counsel represented both Amgen and Teneobio in settlement discussions between the parties. (D.I. 45 at ¶ 3; D.I. 65 at ¶ 3) Teneobio has not identified with any level of specificity the “significant additional resources” to be expended due to the proposed amendment, nor has it articulated how it would be prejudiced by the addition of Amgen after Amgen’s active participation in the litigation for years. (D.I. 190 at 3)

**16. *Judicial estoppel.*** Teneobio argues that Plaintiffs should be judicially estopped from adding Amgen as a defendant because they represented they would not name Amgen as a party or seek damages or injunctive relief from Amgen. (D.I. 190 at 1) Judicial estoppel “prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase.” *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001). Application of the doctrine is appropriate only when there are: “(a) irreconcilably inconsistent positions, (b) adopted in bad faith, and (c) a showing that estoppel addresses the harm and no lesser sanction is sufficient.” *Wirtgen Am., Inc. v. Caterpillar, Inc.*, --- F. Supp. 3d ----, 2024 WL 3888116, at \*2 (D. Del. Aug. 21, 2024) (citing *G-I Holdings, Inc. v. Reliance Ins. Co.*, 586 F.3d 247, 262 (3d Cir. 2009)).

**17.** The “extraordinary remedy” of judicial estoppel is not justified in the instant case. *Montrose Med. Grp. Participating Sav. Plan v. Bulger*, 243 F.3d 773, 784 (3d Cir. 2001). Although Plaintiffs previously represented that they would not seek injunctive relief or damages

against Amgen, this representation was made in their 2022 opposition to Teneobio’s motion to disqualify Plaintiffs’ counsel. (D.I. 50 at 11-13) In correspondence exchanged during briefing on the motion to disqualify, Plaintiffs made clear to Teneobio that they would not “relinquish and waive any and all rights [they] may have now or in the future against Amgen or its affiliates arising out of Teneobio’s infringement of Harbour’s patents.” (D.I. 188, Ex. 3 at 1) Plaintiffs expressly stated that “there is no basis for [Teneobio’s] demand that Harbour waive its rights to seek relief from other entities *regardless of which law firm represents it.*” (*Id.*, Ex. 3 at 2) (emphasis added). For these reasons, the court is not persuaded that “the harshest remedy” of judicial estoppel should apply to bar Plaintiffs from adding Amgen as a defendant. *Montrose*, 243 F.3d at 784.

**18. Futility.** Teneobio argues that Plaintiffs’ proposed amendment to add Amgen is futile because Amgen has a license to the asserted patents. (D.I. 190 at 2) However, “a complaint need not anticipate or overcome affirmative defenses,” and affirmative defenses generally may not be used to dismiss a complaint under Rule 12(b)(6). *Acosta v. DeVilbiss Landscape Architects, Inc.*, C.A. No. 17-354-MN, 2018 WL 5033757, at \*2-3 (D. Del. Oct. 17, 2018) (internal quotation marks and citations omitted); *see Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007). The cases cited by Teneobio in support of its license defense argument did not arise at the pleading stage. *See, e.g., Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872 (Fed. Cir. 1995) (appeal of district court ruling entering a permanent injunction against competitor based on jury verdict of infringement); *Radar Indus., Inc. v. Cleveland Die & Mfg. Co.*, 424 F. App’x 931 (Fed. Cir. 2011) (appeal of district court’s grant of summary judgment for alleged infringer). On this limited record, “th[e] court hesitates to undergo a rigorous 12(b)(6) analysis of the claims alleged to be futile based on less than

complete briefing[.]” *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 736 (D. Del. 2002).

**19.** Teneobio also contends that amendment would be futile because the proposed amended complaint contains only conclusory statements about Amgen’s relationship to Teneobio and does not plausibly allege direct infringement by or at the direction of Amgen. (D.I. 190 at 2) The court finds the facts alleged in the proposed amended complaint are sufficient to plead plausible claims of direct infringement against Amgen under an alter ego or agency theory. *See British Telecommc’ns PLC v. IAC/InteractiveCorp*, 356 F. Supp. 3d 405, 409-10 (D. Del. 2019). Citing to Amgen’s own representations in this case, Plaintiffs plausibly allege that Amgen does not operate Teneobio as an independent business, it makes strategic and legal decisions for Teneobio, and it participates in the marketing, distribution, and further development, use, and commercialization of the allegedly infringing UniRat® platform. (D.I. 188, Ex. 1 at ¶¶ 15-21) These allegations, which are supported by Amgen declarations, press releases, and websites, are sufficient to plead a plausible claim of direct infringement against Amgen under an alter ego or agency theory of liability. *British Telecommc’ns*, 356 F. Supp. 3d at 412.

**20. Conclusion.** For the foregoing reasons, Plaintiffs’ motion for leave to file the amended complaint is GRANTED. (D.I. 200)

**21.** Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties shall jointly submit a proposed redacted version by no later than **February 4, 2025**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material

would “work a clearly defined and serious injury to the party seeking closure.” *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within fourteen (14) days of the date the Memorandum Order issued.

**22.** This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to four (4) pages each.

**23.** The parties are directed to the court’s Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court’s website, [www.ded.uscourts.gov](http://www.ded.uscourts.gov).



Sherry R. Fallon  
United States Magistrate Judge